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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/966,497	09/28/2001	Harry S. Sowden	MCP-294	5321

27777 7590 07/05/2005

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EXAMINER	
ORTIZ, ANGELA Y	
ART UNIT	**PAPER NUMBER**
1732	

DATE MAILED: 07/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/966,497	SOWDEN ET AL.	
	Examiner	Art Unit	
	Angela Ortiz	1732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 April 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12,14-22 and 137* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,14-22 and 137* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 September 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 2, 6-10, 137 are rejected under 35 U.S.C. 102(e) as being anticipated by Rosenberg et al., USP 6,669,883 (already of record).

The cited reference teaches the claimed process of manufacturing a molded dosage form. The detailed method steps include providing a flowable material by first preparing a composition containing a medicament for shaping by conventional means, such as extrusion which is readable on injecting a flowable material through a nozzle, forming the composition by injecting the material into a mold cavity of a molding apparatus. The molding machine shapes the flowable material until the composition is solidified into the shape of the cavity. It is later cooled and solidified. Please see the abstract, col. 2, lines 1-15; col. 3, lines 5-32, 57-67; col. 7, lines 25-67; .

Claim 2, see col. 3, lines 10-15 (cooling by incorporation by reference).

Claim 137, see col. 3, lines 10-13.

Claim 6, see col. 4, lines 25-27.

Claim 7, see col. 5, lines 5-10.

Claim 8 and claim 9, see col. 5, lines 18-20. Claim 10, see col. 4, line 26.

Claims 2-5, 11-12, 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg et al., USP 6,669,883 (already of record).

The cited reference teaches the basic claimed process of manufacturing a solid molded dosage form. The detailed method steps include providing a flowable material by first preparing a composition by including active pharmaceutical ingredients in polymers, the active ingredient in the form of a molecular dispersion in the polymer. The molding machine conventionally includes an upper and lower mold part with a mold cavity inbetween. The molding machine heats the composition to produce a flowable material, and the material is pressed into a mold cavity until the mold is filled, and the composition is solidified into the shape of the cavity. Note that the material is extruded, and is thus readable on the claimed step of injecting into a mold cavity. Please see the abstract, col. 7, lines 25-60; the example at col. 12, lines 33-37 and claims 1-7.

The cited primary reference does not teach the claimed steps of cooling and traveling as claimed.

Note that the reference incorporates by reference plasticizing as performed conventionally in the art at col. 3, lines 8-20. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the step of cooling during hardening to solidify the melted material as is well known in the art.

With respect to claims 2-5, 11, note that the heating and cooling performed includes conventional means; it would have been obvious to further include the conventional means claimed for achieving the desired temperature effect.

With respect to claims 12-13, note that a defect free product is a long-standing felt need in the art of making dosage forms and would have been obvious to include for making an attractive product.

Claims 14-19, 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg et al., USP 6,669,883 in view of Voss, USP 6,177,125 (both of record).

The cited primary reference teaches the basic claimed process of manufacturing a solid molded dosage form. The detailed method steps include providing a flowable material by first preparing a composition by including active pharmaceutical ingredients in polymers, the active ingredient in the form of a molecular dispersion in the polymer. The molding machine conventionally includes an upper and lower mold part with a mold cavity inbetween. The molding machine heats the composition to produce a flowable material, and the material is pressed into a mold cavity until the mold is filled, and the composition is solidified into the shape of the cavity. Note that the material is extruded, and is thus readable on the claimed step of injecting into a mold cavity. Please see the abstract, col. 7, lines 25-60; the example at col. 12, lines 33-37 and claims 1-7.

The cited primary reference does not teach the claimed step of placing an insert in the mold cavity prior to injecting.

The added reference teaches as conventional a method of making coated tablets that comprise a core, the method further including placing the core or insert in the mold cavity prior to complete molding of the tablet. The detailed steps include providing a coating composition in granulate form, adding a core to the granules and molding the

composition into tablet form. One embodiment forms the process in a single step, while additional embodiments partially fill the mold, place the core within the mold and then completely fill the mold to form a coated tablet. Note that the core can be injected. See claims 1-21; col. 1, lines 48-57.

It would to add an insert prior to complete molding of the dosage form, in view of the added reference, when performing the process set forth in the primary reference, for forming an encapsulated tablet. Note that the primary reference prefers a liquid center fill; it would have been obvious to use a non-liquid fill in view of the added reference, for forming an encapsulated tablet in a single process step.

Response to Arguments

Applicant's arguments with respect to claims 1-12, 20-21, and137 have been considered but are moot in view of the new ground(s) of rejection.

Note that the newly added limitations are addressed in the new rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

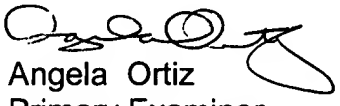
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Angela Ortiz whose telephone number is 571-272-1206. The examiner can normally be reached on Monday-Thursday 9:00-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Colaianni can be reached on 571-272-1196. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Angela Ortiz
Primary Examiner
Art Unit 1732

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